

Radiation Rule Guide

Dental Facilities

Hawaii Administrative Rules,
Chapter 11-45,
Radiation Control



Hawaii State
Department
of Health

Radiation Rule Guide for Dental Facilities

Hawaii Administrative Rules, Chapter 11-45, Radiation Control

**Hawaii State Department of Health
Indoor and Radiological Health Branch
July 2009**

Inquiries:

Hawaii State Department of Health
Indoor and Radiological Health Branch
591 Ala Moana Blvd., Rm. 133
Honolulu, HI 96813

Phone: (808) 586-4700

Fax: (808) 586-5838

Designed by Jeff Eckerd

The information contained in this document is for guidance. The implementation and use of the information and recommendations contained in this document are at the discretion of the user. The implications from the use of this document are solely the responsibility of the user.

The depiction of commercial products, their sources, or their use in connection with material reported herein is not to be construed as either an actual or implied endorsement of such products by the State of Hawaii Department of Health.

Table of Contents

Dental Facility Information	1
Purpose	3
License	4
Shielding Evaluation and Area Radiation Survey	6
Health Physicists and Medical Physicists	8
Radiation Protection Program	10
Lead Aprons and Cervical or Thyroid Collars	12
General Public Dose Limits	12
Occupational Dose Limits	12
Caution Signs	12
Personal Monitoring	14
X-ray Machine Operating Procedures	16
X-ray Machine Performance Standards	18
Radiological Health Inspections	20
Request for Amendment Form	22
Annual Review and Acknowledgement	23
Notes	26

Dental Facility Information

Facility Name _____

Address _____

Dentists _____

Dental Hygienists _____

Dental Assistants _____

**Person Responsible for
Radiation Safety** _____

**X-ray Service
Company** _____

Medical Physicist _____

Purpose

This document is intended to assist dental facilities in complying with the Hawaii Administrative Rules (HAR), Chapter 11-45, Radiation Control. Rule requirements and the policies of our office, the Radiation Program of the State Department of Health's Noise, Radiation and Indoor Air Quality Branch, are summarized and are not intended to include all requirements, but only the major requirements. Therefore, this guide should be used in conjunction with HAR, Chapter 11-45.

Dental facilities may utilize this document as a radiation protection program and as a part of their standard operating procedure where all providers and employees are required to review, implement, and acknowledge all specific requirements on an annual basis.

License

HAR, Chapter 11-45 requires a ***Radiation Facility License*** for all dental facilities with ionizing radiation-producing machines **before** installation, possession, or use of such machines.

All parties selling, leasing, installing, or servicing dental x-ray machines, or providing health physics services or medical physics services, are also required to have a ***Radiation Service License*** **before** such services are rendered to dental facilities.

A completed ***Application for Radiation Facility/Services License*** is submitted with the appropriate fee at least sixty days **before** the intended possession of dental x-ray machines or provision of radiation services to our office.

Application fees are as follows:

Dental facility with one to four x-ray machines	\$30
Dental facility with more than four x-ray machines	\$50
Radiation services	\$30

A ***Radiation Facility License*** for a dental facility is issued for a period of two years. The license is posted in a location that is visible to users of the dental facility. Dental facilities renew their licenses by March 31st on even years.

A ***Radiation Service License*** is issued for a period of two years. There is no posting requirement. Service entities renew their licenses by March 31st on odd years.

The accompanying ***Appendix to License*** listing contact and responsibility information and sources of radiation/services, and a copy of HAR, Chapter 11-45, are required to be on file at the facility.

The licensee provides notification to our office of any changes in the number or type of x-ray machines or any information specified on the license on a ***Request for Amendment*** form (see page 22.) The completed form can be faxed or mailed to our office.

Reference: HAR, Chapter 11-45, Sections 11-45-17 through 11-45-31

Radiation Rule Guide Checklist

	Yes	No
Do you have a Radiation Facility License for your dental facility?	<input type="checkbox"/>	<input type="checkbox"/>
Does the entity that will install and service your dental x-ray machine have a current Radiation Service License?	<input type="checkbox"/>	<input type="checkbox"/>
Is your Radiation Facility License posted in a location visible to patients?	<input type="checkbox"/>	<input type="checkbox"/>
Do you have the Appendix to License and a copy of HAR, Chapter 11-45, on file?	<input type="checkbox"/>	<input type="checkbox"/>
Is the information on your License and your Appendix to License current?	<input type="checkbox"/>	<input type="checkbox"/>
Did you renew your License before the expiration date?	<input type="checkbox"/>	<input type="checkbox"/>



Shielding Evaluation and Area Radiation Survey

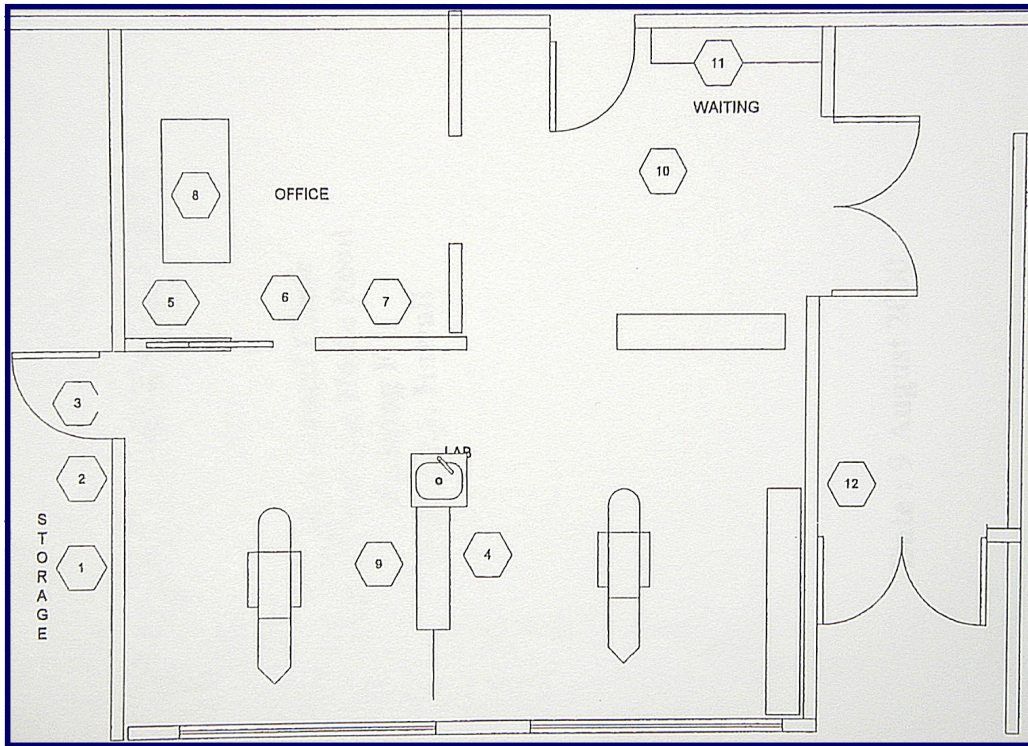
The ***Shielding Evaluation*** is conducted in the pre-construction phase based on the architectural plan and the position of the radiation-emitting device. This is **optional** for dental facilities.

The **Area Radiation Survey** is a required post-construction radiation survey to determine the adequacy of the original shielding design or building materials used in the construction of a dental facility. This survey is conducted within six months after the dental facility becomes operational. A copy of the survey report is sent by the licensee to our office.

An **Area Radiation Survey** is **not** required for new facilities or renovation of existing dental facilities with only a dental panoramic unit without cephalometric capability.

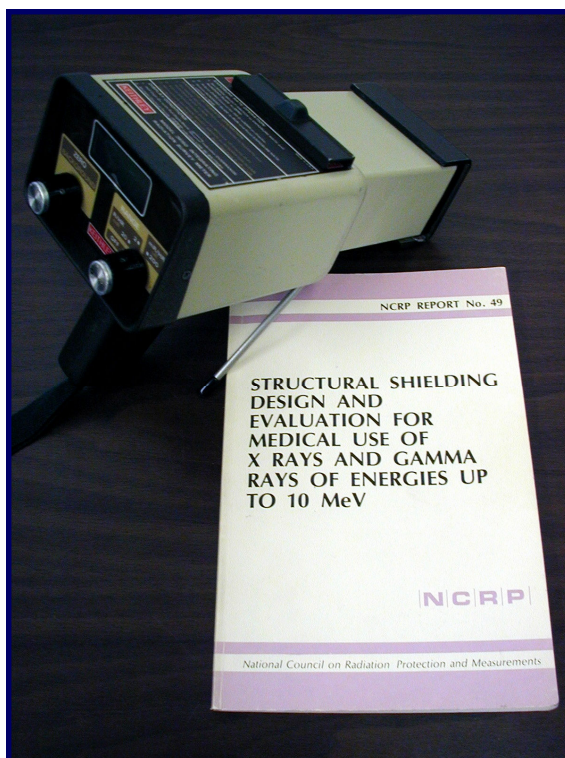
Shielding Evaluations and **Area Radiation Surveys** are required to be conducted by health physicists or medical physicists operating under a **Radiation Facility License** or **Radiation Service License** issued by the Department of Health pursuant to HAR, Chapter 11-45.

Reference: HAR, Chapter 11-45, Sections 11-45-32 through 11-45-34



Radiation Rule Guide Checklist

	Yes	No
For dental facilities built or renovated after 1991:		
Was an Area Radiation Survey performed by a licensed health or medical physicist within six months of commencing operations?	<input type="checkbox"/>	<input type="checkbox"/>
Do you have the Area Radiation Survey report on file?	<input type="checkbox"/>	<input type="checkbox"/>
Have you updated your Area Radiation Survey for any changes in the number of x-ray machines, x-ray examination workload, walls, doors, change in chair position, change in x-ray machine since the initial Area Radiation Survey?	<input type="checkbox"/>	<input type="checkbox"/>



Health Physicists and Medical Physicists

Health physicists and medical physicists, who conduct ***Shielding Evaluations, Area Radiation Surveys***, and other surveys required by HAR, Chapter 11-45, shall be under a ***Radiation Facility License*** or a ***Radiation Service License*** issued by the Department of Health pursuant to HAR, Chapter 11-45.

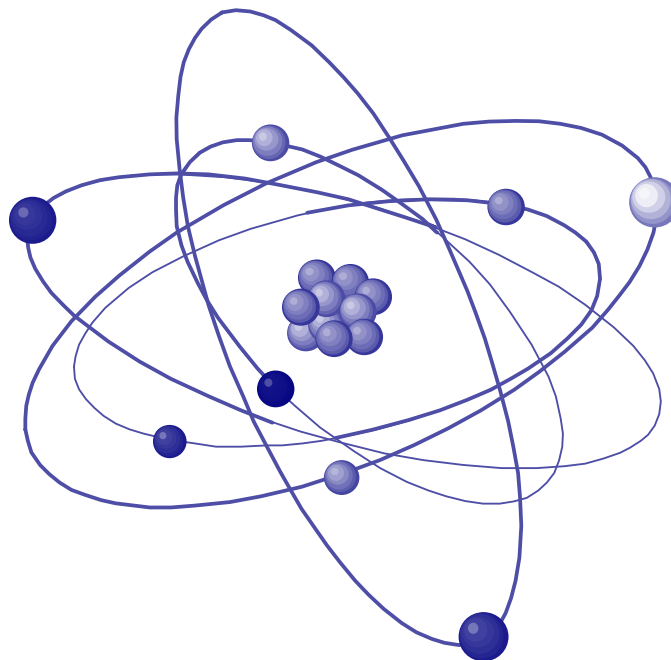
For your convenience, locally available, licensed physicists are as follows:

Philip Manly/Ronald Frick
Gamma Corporation
850 W. Hind Drive, #116
Honolulu, HI 96821
808-373-7009

Mahendra Patel
95-620 Makaimoimo Street
Mililani, HI 96789
808-623-4723

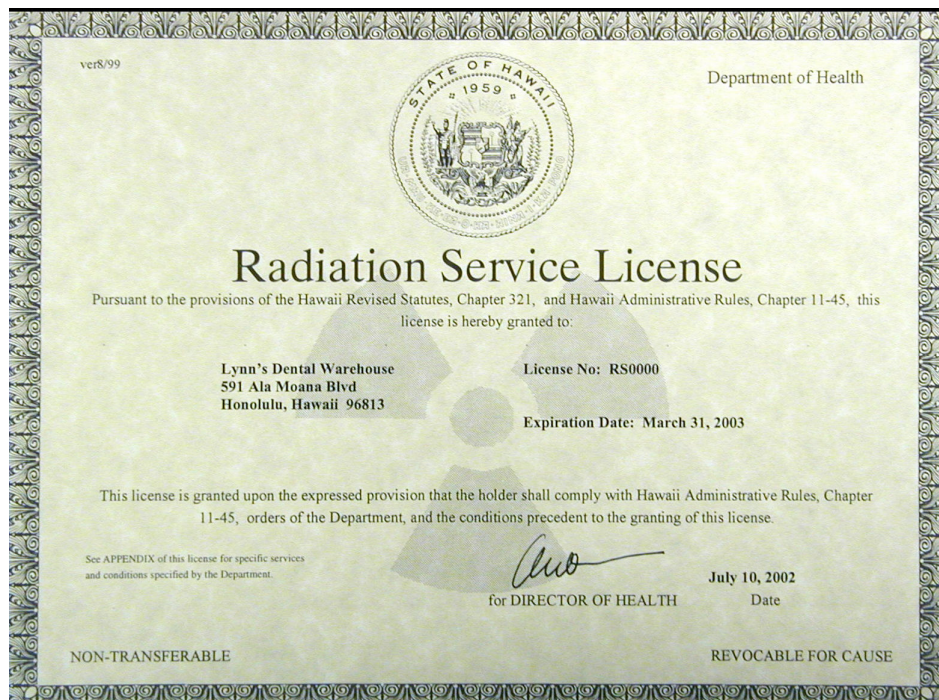
If you are interested in a list of out-of-state physicists, please call our office.

Reference: HAR, Chapter 11-45, Sections 11-45-17 through 11-45-31, 11-45-200 through 11-45-203



Radiation Rule Guide Checklist

	Yes	No
Is your health physicist or medical physicist under a Radiation Facility License or Radiation Service License?	<input type="checkbox"/>	<input type="checkbox"/>



Radiation Protection Program

A radiation protection program is required. Dental facilities may utilize this Rule Guide as a program, or develop and implement a program which is equivalent or better than the Rule Guide. A radiation protection program shall be reviewed at least annually. Dental facilities opting to use this Rule Guide as the radiation protection program shall have all employees read and sign the ***Annual Review and Acknowledgement*** page at the end of the Rule Guide initially and thereafter, annually.

Dental facilities shall use procedures and engineering controls to achieve occupational and general public doses that are as-low-as-is-reasonably-achievable (ALARA).

Reference: HAR, Chapter 11-45, Section 11-45-39



Radiation Rule Guide Checklist

	Yes	No
Do you have a written Radiation Protection Program?	<input type="checkbox"/>	<input type="checkbox"/>
If no:		
Are you are planning to use this Rule Guide as a Radiation Protection Program?	<input type="checkbox"/>	<input type="checkbox"/>
Have all of your employees reviewed this Rule Guide and completed the Annual Review and Acknowledgement page initially, and thereafter, annually?	<input type="checkbox"/>	<input type="checkbox"/>



Lead Aprons and Cervical or Thyroid Collars

The Hawaii Board of Dental Examiners requires the use of lead aprons for patients undergoing x-rays. Cervical or thyroid collars are recommended.

Reference: HAR, Chapter 16-79, Dentists and Dental Hygienists, Section 16-79-7

General Public Dose Limits

The annual limit for individual members of the public is 100 millirems, or 2 millirems in any one hour.

Reference: HAR, Chapter 11-45, Section 11-45-48

Occupational Dose Limits

The annual limit for adults is 5 rems, or 5,000 millirems. The annual limit for a minor is ten percent of the adult dose limit, or 500 millirems. The embryo/fetus dose limit is 500 millirems for the entire gestational period.

Reference: HAR, Chapter 11-45, Sections 11-45-40 through 11-45-47

Caution Signs

A dental facility is not required to post a ***“Caution, Radiation Area”*** sign for an operatory or room with a dental x-ray machine. This is specifically identified in Chapter 11-45.

Secondly, a ***“Caution, Radiation Area”*** sign shall not be placed on dental x-ray machines.

Reference: HAR, Chapter 11-45, Section 11-45-65

Radiation Rule Guide Checklist

	Yes	No
Do you have a lead apron?	<input type="checkbox"/>	<input type="checkbox"/>
Are lead aprons used for all patients undergoing x-ray examination?	<input type="checkbox"/>	<input type="checkbox"/>



Personal Monitoring

Individual monitoring of occupational dose is required under the following conditions:

1. If the external dose for an adult in one year is likely to exceed ten percent of the occupational dose limit, or 500 millirems;
2. If the external dose for a minor in one year is likely to exceed ten percent of the occupational dose limit, or 50 millirems; or
3. If the dose to an embryo/fetus is likely to exceed ten percent of the embryo/fetus dose, or 50 millirems.
4. For individuals entering a high or very high radiation area.

Individual monitoring can be accomplished with various dosimeters. The most common dosimeter is the film type, which can be kept as a physical record after processing and reading. There is also the thermoluminescent dosimeter or the TLD which cannot be kept as a physical record after processing and reading. The newest technology is optically-stimulated luminescence, or OSL. Many OSL badges are replacing the film type.

Dosimeters are normally worn on the torso between the neck and the waist.

Dosimeters are usually sent to the dosimetry processor at the end of a specific period for dose assessment. The period can be every month, every two months, or quarterly.

No matter which type of dosimeter is utilized, all dosimeters shall be processed and evaluated by a processor holding a current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology (NIST).

Dosimeters are usually sent to a facility with a “control” badge. This is used to monitor radiation exposure in transit. “Control” badges should be kept in an area with no radiation. Many times, our inspectors find “control” badges stored in x-ray rooms.

Individual monitoring records shall be kept by the dental facility.

The person responsible for radiation safety at a dental facility reviews the periodic exposure reports upon receipt to ensure no one has exceeded the occupational limits. If anyone has exceeded the occupational limits, the Department of Health shall be notified as soon as possible.

Based on shielding evaluations and area radiation surveys conducted in Hawaii, very few dental facilities require individual monitoring. However, a small number of facilities not required to monitor their employees’ dose use dosimeters to ensure that the radiation in their facility is minimal and below ten percent of the occupational dose.

Reference: HAR, Chapter 11-45, Sections 11-45-53, 11-45-54, 11-45-83, 11-45-89, 11-45-90, 11-45-95, 11-45-191

Radiation Rule Guide Checklist

	Yes	No
Is individual monitoring required for your dental facility? (The requirement for monitoring is normally indicated in the Area Radiation Survey report.)	<input type="checkbox"/>	<input type="checkbox"/>
Do you use individual monitoring at your facility even though it is not required?	<input type="checkbox"/>	<input type="checkbox"/>
Are periodic exposure reports reviewed by the person responsible for radiation safety in your facility upon receipt to ensure exposure is below the occupational limit?	<input type="checkbox"/>	<input type="checkbox"/>
Are you maintaining personnel monitoring records?	<input type="checkbox"/>	<input type="checkbox"/>
Are you notifying your employees regarding their dose at least annually?	<input type="checkbox"/>	<input type="checkbox"/>
Is the “control” badge kept in a non-radiation area?	<input type="checkbox"/>	<input type="checkbox"/>



X-ray Machine Operating Procedures

Operators shall be trained on the operating procedures for each specific dental x-ray machine. The manufacturer's operating manual shall be available to all operators. The manufacturer's recommendations shall be followed. The operator shall be in a protected position during exposure. Techniques for exposure shall be available to the operator at the x-ray control assembly.

X-ray machine operators in dental facilities are under the jurisdiction of the Board of Dental Examiners. Aside from dentists, dental hygienists and dental assistants are usually trained to do x-ray examinations in dental facilities.

If a patient or film requires auxiliary support, patient holding and holding devices shall be utilized. Written procedures for patient holding and use of holding devices shall be available to the operator. No individual shall be used to routinely hold patients. Individuals holding patients shall be shielded or protected by a lead apron and gloves.

Records shall be maintained for each dental x-ray machine to include, operator's manual, tube rating charts, cooling curves, inspections, calibrations, maintenance, and modifications.



An x-ray examination log or patient record shall be utilized to record a patient's x-ray examination. This can be in hard copy or on a computer database.

Film, film processing, whether manual or automatic, shall be used/conducted according to the manufacturer's recommendations. Equipment necessary to conduct film processing shall be available in a dental facility.

Darkrooms shall be light tight. Safe lights shall be appropriate for the film utilized in the dental facility.

Reference: HAR, Chapter 11-45, Sections 11-45-116, 11-45-120; HAR, Chapter 16-79, Dentists and Dental Hygienists, Sections 16-79-69.1 and 69.10

Radiation Rule Guide Checklist

	Yes	No
Do you have the manufacturer's operating manual for each dental x-ray machine?	<input type="checkbox"/>	<input type="checkbox"/>
Do you have records for each dental x-ray machine relative to calibration, maintenance, or modifications?	<input type="checkbox"/>	<input type="checkbox"/>
Do you have a written procedure for the use of patient holding or holding devices?	<input type="checkbox"/>	<input type="checkbox"/>
Do you have x-ray examinations recorded on an x-ray examination log or patient record?	<input type="checkbox"/>	<input type="checkbox"/>
Are your operators of dental x-ray machines instructed on the use of each dental x-ray machine in your facility?	<input type="checkbox"/>	<input type="checkbox"/>
Are technique settings for each dental x-ray machine available to each operator?	<input type="checkbox"/>	<input type="checkbox"/>
Are your operators of dental x-ray machines making exposures from a protected position?	<input type="checkbox"/>	<input type="checkbox"/>
Do you have all requisite equipment and supplies for film processing?	<input type="checkbox"/>	<input type="checkbox"/>
Are you following manufacturer's recommendations for film, film processing chemicals, automatic film processors, and disposal of old fixer and developer solutions?	<input type="checkbox"/>	<input type="checkbox"/>

X-ray Machine Performance Standards

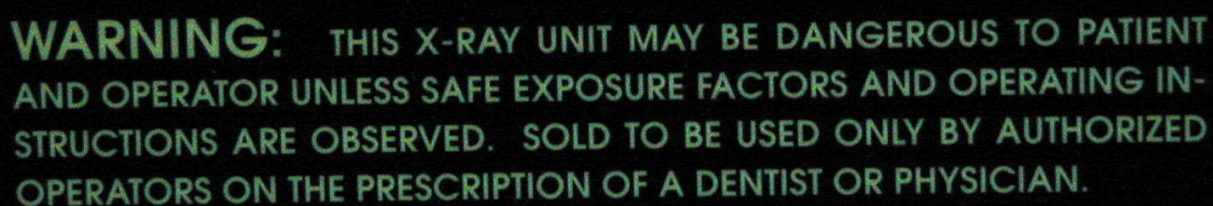
All x-ray machines used for diagnostic purposes in the practice of dentistry shall meet the performance standards pursuant to HAR, Chapter 11-45.

Performance standards cover various items relating to the safety and exposure of dental x-ray machines. These include a warning label (“Warning: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed.”) exposure reproducibility within 5%, exposure linearity of tube current and/or the product of tube current and exposure duration within 10%, minimum half-value layer (HVL,) exposure termination at the preset time, visual and audible indication of exposure.

For intraoral x-ray machines, the source-to-skin distance (SSD) shall not be less than eighteen centimeters, the x-ray field at SSD shall be no greater than seven centimeters, and the tube housing and position-indicating-device (PID) shall be stable at predetermined positions.

Performance standards are usually checked during the Department of Health’s periodic radiological health inspections.

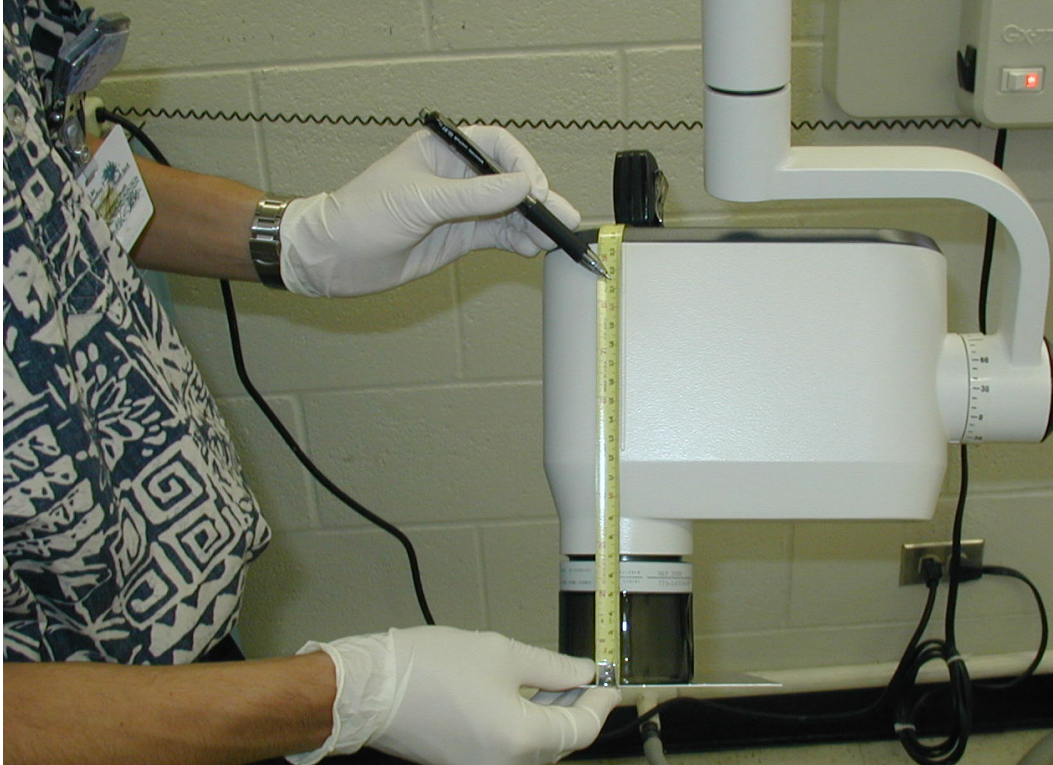
Reference: HAR, Chapter 11-45, Sections 11-45-117, 11-45-120



WARNING: THIS X-RAY UNIT MAY BE DANGEROUS TO PATIENT AND OPERATOR UNLESS SAFE EXPOSURE FACTORS AND OPERATING INSTRUCTIONS ARE OBSERVED. SOLD TO BE USED ONLY BY AUTHORIZED OPERATORS ON THE PRESCRIPTION OF A DENTIST OR PHYSICIAN.

Radiation Rule Guide Checklist

	Yes	No
Is there a warning label on the control assembly of your dental x-ray machine?	<input type="checkbox"/>	<input type="checkbox"/>
Are your exposures consistent relative to contrast?	<input type="checkbox"/>	<input type="checkbox"/>
Do the tube head and the PID remain in position for specific x-ray examinations without drifting or moving?	<input type="checkbox"/>	<input type="checkbox"/>
Have you resolved or repaired all problems relative to your dental x-ray machine?	<input type="checkbox"/>	<input type="checkbox"/>



Radiological Health Inspections

Radiological health inspections are conducted every three to five years for dental facilities routinely during working hours. The inspection includes a review of the facility license record, a review of the initial area radiation survey report, performance standards testing of dental x-ray machines, and a review of required records. An inspection report is subsequently rendered. Any shortcomings identified during the inspection are listed with a specification for corrective action.

Inspection reports shall be posted within five working days of receipt for five working days for employees of the dental facility. In lieu of posting, the licensee may keep the inspection report on file and inform employees of its availability.

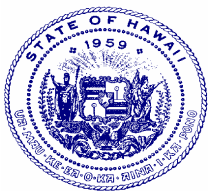
Copies of written notices of corrective action shall also be posted within five working days after mailing for five working days. In lieu of posting, the licensee may keep the written notice of corrective action on file and inform employees of its availability.

Reference: HAR, Chapter 11-45, Sections 11-45-6, 11-45-189



Radiation Rule Guide Checklist

	Yes	No
Do you have Department of Health radiological health inspection reports on file?	<input type="checkbox"/>	<input type="checkbox"/>
Are all shortcomings or discrepancies identified by the Department of Health corrected?	<input type="checkbox"/>	<input type="checkbox"/>
Do you have a copy of all written notifications of corrective action sent to the Department of Health?	<input type="checkbox"/>	<input type="checkbox"/>



State of Hawaii - Department of Health
Indoor and Radiological Health Branch

REQUEST FOR AMENDMENT
RADIATION FACILITY / SERVICES LICENSE

Part I. Facility / Service License Number

Part II. Facility / Service Name and Address

☐ D.B.A.

☐ Owner / Lessee / User

Name of Facility

Telephone

Street Address

Persons Responsible for Radiation Safety

City

State

Zipcode

Medical Physicist / Health Physicist

Mailing Address

Facility Compliance Contact

City

State

Zipcode

Facility Inspection Contact

Part III. Radiation Producing Equipment (attach addl. sheets as needed)

☐ No Radiation Producing Equipment

ADD/	Manufacturer	Control Model No.	Control Serial No.	Manufacture	Room	Purpose or Use

Part IV. Radioactive Materials (attach additional sheets as needed)

☐ No Licensable Radioactive Material

ADD/	Isotope	Sealed?:	Source Strength	Estimated Quantity	Avg. Quantity	Purpose or Use

Part V. Other (Changes that are not listed on this sheet)

I declare that all the information appearing on this license amendment request is accurate and true to the best of my knowledge.

X
Signature of facility owner/lessee/user/authorized agent

Date _____

FOR OFFICE USE ONLY

Date Received: _____

Amendment: **Approved / Disapproved**

License Expires: _____

FAX or Return this application to:

Indoor and Radiological Health Branch
591 Ala Moana Boulevard
Honolulu, Hawaii 96813-4921
FAX: (808) 586-5838

If you have any questions, please call our office at (808) 586-4700.

Form IRHB-RAD102.1 02/08

Annual Review and Acknowledgement

Name

Signature

Date

[illegible]

Annual Review and Acknowledgement

Name

Signature

Date

[illegible]

Annual Review and Acknowledgement

Name

Signature

Date _____

This image shows a full page of blank, lined paper. It features approximately 20 evenly spaced horizontal grey lines across its entire width, providing a template for writing or drawing. The margins are consistent on all sides.

Notes

Notes

Notes

Notes

Notes

Notes



Hawaii State Department of Health
JULY 2009